5. 510(K) SUMMARY

Submitter:	Emerge Medical
Submitter's Name:	Michelle Potvin, Vice President of Quality Assurance michelle.potvin@emergemedical.com
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Contact Person:	Meredith L. May MS, RAC 719.337.7579 MMay@EmpiricalTesting.com
Date Summary was Prepared:	15 January 2014
Trade or Proprietary Name:	Emerge Medical Periarticular and Locking Large Fragment System
Common or Usual Name:	Single/multiple component metallic bone fixation appliances and accessories (§888.3030), Smooth or threaded metallic bone fixation fastener (§888.3040)
Classification:	Class II per 21 CFR §888.3030 and §888.3040
Product Code:	HRS and HWC
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Emerge Medical Periarticular and Locking Large Fragment System consists of implants and instruments designed to be used for internal bone alignment and fixation of fractures of the tibia and femur. The system features four (4) types of plates (4.5mm Locking Proximal Tibia Plate, 4.5 Locking Condylar Plate, Locking 4.5mm Narrow and Broad Plate, Locking T-Plate), bone screws for fixation, and a set of instruments to facilitate installation and removal of the implants. The plates have screw holes, which allow for attachment to the bones or bone fragments. The plates are fabricated from medical grade stainless steel (ASTM F139), and offered in various widths, lengths, and thicknesses. Plates and screws are provided non-sterile.

TECHNOLOGICAL CHARACTERISTICS

The Emerge Medical Periarticular and Locking Large Fragment System has the same or similar design, sizes, indications for use, and materials as the predicate systems. The sizes differ slightly, but present no new risks.

INDICATIONS FOR USE

The indications for the Emerge Medical Periarticular and Locking Large Fragment System are as follows for the two subsystems:

The Emerge Medical Periarticular Locking Plate Set is intended for treatment of nonunions, mal unions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, periprosthetic fractures, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures. The Periarticular Locking Plate Set is also intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular Condylar fractures, fractures in normal or osteopenic bone, periprosthetic fractures, and nonunions and malunions.

The Emerge Medical Locking Large Fragment Set is intended for fixation of various long bones, such as the humerus, femur, and tibia. Emerge Medical Locking Large Fragment Set is also intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau, and distal tibia. The set is also for use in fixation of periprosthetic fractures, osteopenic bone, and nonunions or malunions.

The Emerge Medical Periarticular and Locking Large Fragment System is not intended for use with active or latent infection, osteoporosis, insufficient quantity or quality of bone/soft tissue, material sensitivity (if suspected tests should be performed prior to implantation), sepsis, patients who are unwilling or incapable of following postoperative care instructions. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

The indication for use for the Emerge Medical Periarticular and Locking Large Fragment System is similar to that of the predicate devices listed in Table 5-1 Predicate Devices.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**
K082807	3.5mm and 4.5mm Locking Compression Plate (LCP) System with Expanded Indications	Synthes
K000682, K041911	Locking Fragment Dynamic Compression Locking (DCL) System, LCP Curved Plates	Synthes
K000066	Locking Condylar Plate (LCP) System	Synthes
K110354, K083025	4.5mm VA-LCP Curved Condylar Plate System	Synthes
K062564	LCP Distal Femur Plate	Synthes
K010766	Large Fragment Locking Compression Plate (LCP) System – T Plate	Synthes
K011978, K002361, K983787	LCP Proximal Tibia Plate, Locking Proximal Tibia Plating (L-PTP) System, Proximal Tibia Plating System	Synthes

PERFORMANCE DATA

The Emerge Medical Periarticular and Locking Large Fragment System were evaluated via finite element analysis (FEA) demonstrative the predicate was the worst case scenario. The folloing test modes were emulated on the worst-case plates and screws through FEA:

- Static four-point bending per ASTM F382-99
- Dynamic four-point bending per ASTM F382-99
- Static screw pull-out per ASTM F543-13
- Static torsion per ASTM F543-13

The results of this non-clinical testing show that the strength of the Emerge Medical Periarticular and Locking Large Fragment System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Emerge Medical Periarticular and Locking Large Fragment System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 12, 2014

Emerge Medical
%.Ms. Meredith May MS, RAC
Senior Manager
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K140119
Trade/Device Name: Emerge Medical Periarticular and Locking Large Fragment System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 15, 2014
Received: January 16, 2014

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: December 31, 2013 *See PRA Statement on last page.*

510(k) Number *(if known)* K140119

Device Name
Emerge Medical Periarticular and Locking Large Fragment System

Indications for Use (*Describe*)

The indications for the Emerge Medical Periarticular and Locking Large Fragment System are as follows for the two subsystems:

The Emerge Medical Periarticular Locking Plate Set is intended for treatment of nonunions, mal unions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, periprosthetic fractures, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures. The Periarticular Locking Plate Set is also intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular Condylar fractures, fractures in normal or osteopenic bone, periprosthetic fractures, and nonunions and malunions.

The Emerge Medical Locking Large Fragment Set is intended for fixation of various long bones, such as the humerus, femur, and tibia. Emerge Medical Locking Large Fragment Set is also intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau, and distal tibia. The set is also for use in fixation of periprosthetic fractures, osteopenic bone, and nonunions or malunions.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth L Frank -S

Division of Orthopedic Devices

FORM FDA 3881 (9/13)

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